

4. (Amended) A formulation according to claim 3 wherein the water soluble film forming polymer is a polymer that has an apparent viscosity of 1 to 100 mPa.s.
5. (Amended) A formulation according to claim 4 wherein the water soluble polymer is selected from
- (a) alkylcelluloses,
 - (b) hydroxyalkylcelluloses,
 - (c) hydroxyalkyl alkylcelluloses,
 - (d) carboxyalkylcelluloses,
 - (e) alkali metal salts of carboxyalkylcelluloses,
 - (f) carboxyalkylalkylcelluloses,
 - (g) carboxyalkylcellulose esters,
 - (h) starches,
 - (i) pectines,
 - (j) chitine derivatives,
 - (k) polysaccharides,
 - (l) polyacrylic acids and the salts thereof,
 - (m) polymethacrylic acids and the salts thereof, methacrylate copolymers,
 - (n) polyvinylalcohol,
 - (o) polyvinylpyrrolidone, copolymers of polyvinylpyrrolidone with vinyl acetate, or
 - (p) polyalkylene oxides.

9. (Amended) A formulation according to claim 8 wherein the inert spheres are 16-60 mesh sugar spheres.

11. (Amended) A formulation according to claim 10 wherein the water insoluble polymer is ethylcellulose and the plasticizer is selected from the group consisting of dibutyl sebacate, diethyl phthalate and triethyl citrate.

14. (Amended) A formulation according to claim 1 further comprising a topcoat comprising galantamine and water-soluble polymer.
15. (Amended) A formulation according to claim 14 capable of releasing from 20 to 40 % of the total amount of galantamine.HBr in 1 hour, and more than 80 % of the total amount of galantamine.HBr in 10 hours.
16. (Amended) A dosage form comprising a therapeutically effective amount of the controlled release formulation of claim 1.
19. (Amended) A dosage form according to claim 18 wherein said immediate release form comprises particles comprising galantamine or a pharmaceutically acceptable acid addition salt thereof, and a water soluble pharmaceutically acceptable excipient.
21. (Amended) A dosage form according to claim 18 wherein said immediate release form comprises said controlled release formulation, and a topcoat comprising galantamine and water-soluble polymer.
23. (Amended) A pharmaceutical package comprising a container, a formulation of galantamine as claimed in claim 1, and written matter specifying how said formulation should be administered.
24. (Amended) A pharmaceutical package as claimed in claim 23 adapted for treating a patient who is acetylcholine esterase inhibitor-naïve, comprising 21-35 daily sequential dosage units of
- (a) a first group of 7 to 14 dosage units comprising from 5 to 10 mg galantamine,
 - (b) a second group of 7 to 14 dosage units comprising from 10 to 20 mg galantamine,
 - (c) a third group of 7 to 14 dosage units comprising from 15 to 30 mg galantamine, and
 - (d) optionally a fourth group of 7 dosage units comprising from 20 to 40 mg galantamine.

25. (Amended) A pharmaceutical package as claimed in claim 23 adapted for treating a patient who is acetylcholine esterase inhibitor-tolerant, comprising daily dosage units comprising from 15 to 30 mg galantamine.

27. (Amended) A method of treating Alzheimer's dementia and related dementias in a human while substantially reducing the concomitant liability of adverse effects associated with acetyl cholinesterase inhibitors, comprising administering to a human in need of such treatment, a therapeutically effective amount of galantamine in a controlled release formulation as claimed in claim 1, said amount being sufficient to alleviate said Alzheimer's dementia and related dementias, but insufficient to cause said adverse effects.

28. (Amended) A method according to claim 27 wherein the related dementia is selected from the group consisting of vascular dementia, Lewy body disease, autism, mental retardation, bipolar disorder psychiatric conditions, disruptive behaviour, attention deficit, hyperactivity disorder, substance abuse, extreme aggression, especially conduct disorder, nicotine cessation and withdrawal.

29. (Amended) A method according to claim 27 wherein the adverse effects are selected from the group consisting of nausea, vomiting, sweating, restlessness, and insomnia.

Please add claim 30 as follows:

30. (New) A formulation according to claim 5 wherein the water soluble polymer is selected from the group consisting of methylcellulose, hydroxymethylcellulose, hydroxyethylcellulose, hydroxypropylcellulose, hydroxybutylcellulose, hydroxyethyl methylcellulose, hydroxypropyl methylcellulose, carboxymethylcellulose, sodium carboxymethylcellulose, carboxymethylethylcellulose, sodium carboxymethylamylopectine, chitosan, alginic acid, alkali metal and ammonium salts thereof, carrageenans, galactomannans, traganth, agar-agar, gummi